

**PART B**

**USING THE PUBLIC HEALTH FRAMEWORK:**

**A DETAILED ANALYSIS OF FOOD SAFETY LAWS IN**

**MONTANA**

**DRAFT ONLY**

In this review of Montana's Food Safety Laws, we have adopted the Framework and Principles on Food and Consumer Safety which are set out in our main Report in Part A. We commenced this review of Montana's Food Safety Laws by assessing the legislative competence of the Federal and State governments in the US and confirming the legislative authority of Montana in relation to food safety issues: see Part 2 below. Taking into account the constitutional limits of Montana's legislative authority, we then surveyed the alternative regulatory options for food safety which exist in the United States and in other similar jurisdictions and which are options for Montana to consider in any reform of its laws: see Part 3 below. Within the boundaries provided by the Framework and Principles, we selected our preferred regulatory models from the survey in Part 3 and evaluated Montana's food safety laws in light of these models: see Part 4. Our findings regarding Montana's Food Safety Laws are summarized in the main Report in Part A.

**2. FEDERALISM AND THE ROLE OF THE STATE**

In this review of Montana's Food Safety Laws, it is essential to start by understanding the legislative competence of the Federal and State governments in the area of food safety. Montana should only enact laws within the boundaries of its legislative authority. Most aspects of food safety are subject to Federal authority alone or concurrent Federal and State legislative power. There are limited aspects of food safety that are within the exclusive competence of the State.

Where the Federal and State governments have concurrent power, the Federal government may have expressly preempted State legislation that differs from the applicable Federal legislation. This means that the State is prevented from enacting statutes or regulations that impose requirements of a higher standard or, in other cases, of a lower standard than the Federal statute or regulations. Federal laws may also impliedly preempt the State's laws. To avoid problems with preemption, some States enact the same standards as those set by Federal statute or regulations. Other States, such as California, have applied for exemptions from express preemption restrictions.

Table 1 sets out the respective law-making authority of Federal and State legislatures in relation to certain aspects of food safety and the legislative activity of Montana in relation to food safety.

**TABLE 1**

| Area | Federal v State Legislative Power  | Montana's legislation   |
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| Meat | <p>- Federal legislation: No 'additional' or 'different' state requirements are permitted with respect to premises, facilities and operations of establishments at which inspection of meat is permitted (being places where meat is slaughtered, packed, canned, rendered or similar) ('Inspection Establishments').</p> <p>- Federal legislation: No 'additional' or 'different' state requirements are permitted with respect to marking, labeling, packaging or ingredient requirements for meat.</p> <p>- Federal legislation: State may exercise concurrent jurisdiction over meat for the purpose of preventing the distribution of articles which are adulterated or misbranded and <b>outside of</b> Inspection Establishments.</p> <p>- Federal legislation: State may exercise concurrent jurisdiction over meat for the purpose of preventing the distribution of articles which are adulterated or misbranded and are imported products which are not at Inspection Establishments.</p> | <p>- MT has legislative provisions re wholesale food establishments and retail food establishments, but slaughterhouses, meat packing plants or meat depots are excluded from ambit of this legislation. Therefore, MT is clearly within federal requirement that no different or additional requirements be imposed by the states.</p> <p>- The MT legislation prohibits adulteration and misbranding of food. Therefore, MT is also within the federal allowance that states may exercise concurrent jurisdiction over meat (outside of Inspection Establishments) to prevent distribution of adulterated or misbranded food.</p> <p>- It seems these state laws are equally applicable to imported foods.</p> <p>- Is it open to MT to impose the same requirements re slaughterhouses and meat processing plants as the Fed government and still be within Fed law?</p> |
| Eggs | <p>- Federal legislation: No 'additional' or 'different' state requirements are permitted with respect to premises, facilities and operations of official egg plants.</p> <p>- Federal legislation: no additional or different state requirements re standards of quality, condition, quantity or grade, temperature requirements for eggs packaged for the ultimate consumer, labeling requirement regarding the state or other geographical area of production.</p> <p>- Federal legislation: Labeling, packaging or ingredient requirements in addition to or different from those under federal law for eggs processed at an official plant.</p> <p>- Federal legislation: state may require</p>   | <p>- Montana has brought some Federal regulations into state law, including those specifically dealing with eggs, as well as those to do with labelling.</p> <p>- MT needs to take care that egg processing plants not subjected to higher standards of regulation than under Fed law. Egg processing plants in MT could fall under rules for wholesale and retail food establishments.</p> <p>- MT does not impose the requirement that eggs be bear the name, address and licence number of person processing or packaging the eggs. It is open to MT to do this.</p> <p>- MT does have laws relating to adulteration and misbranding, which if applied outside of an official plant,</p>   |

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|  | <p><i>the name, address and licence number of the person processing or packaging the eggs.</i></p> <p><i>- Federal legislation: State may exercise jurisdiction over eggs for the purpose of preventing the distribution of articles which are adulterated or misbranded and <b>outside of</b> an official plant.</i></p>   | would be within the power accorded to it.   |
| Poultry  | <p><i>Federal legislation: No 'additional' or 'different' state requirements are permitted with respect to premises, facilities and operations of any official poultry establishment.</i></p> <p><i>- Federal legislation: No 'additional' or 'different' state requirements are permitted with respect to marking, labeling, packaging or ingredient requirements for poultry.</i></p> <p><i>- Federal legislation: State may exercise concurrent jurisdiction over poultry for the purpose of preventing the distribution of articles which are adulterated or misbranded and <b>outside of</b> official poultry establishments.</i></p> <p><i>- Federal legislation: State may exercise concurrent jurisdiction over meat for the purpose of preventing the distribution of articles which are adulterated or misbranded and are imported products which are not at official poultry establishments.</i></p> | <p>- MT has legislative provisions re wholesale food establishments and retail food establishments, which would cover poultry establishments. MT needs to take care that poultry processing plants not subjected to higher standards of regulation than under Fed law.</p> <p>- MT has brought fed regulations relating to labeling into state law. It does not impose any additional labeling reqs re poultry. It is therefore within Fed law.</p> <p>- The MT legislation prohibits adulteration and misbranding of food. To the extent that MT does not apply these requirements to poultry processing plants, MT is also within the federal allowance that states may exercise concurrent jurisdiction over poultry to prevent distribution of adulterated or misbranded food.</p> <p>- It seems these state laws are equally applicable to imported foods.</p> |
| Foods other than meat, eggs, poultry – non-labeling reqs | <p><i>Concurrent power. No express preemption. Approach has been to allow states to impose stricter standards than any Federal rules as long as the State rules do not conflict with the Federal rules.</i></p>   | Montana overwhelmingly uses Fed standards by way of bringing federal regulations into state law. Montana has also used the 1999 version of the FDA Food Code. It is open for Montana to set higher standards than the Federal government.   |
| Nutrition labeling                                       | <p><i>No state may establish a standard of identity or type of labeling which is not identical to the fed standard, unless it has been exempted from the requirement on the basis that the state requirement would not cause the food to be in violation of any applicable requirement under Federal law, would not unduly burden interstate commerce and is designed to meet a particular need for information which is not met by the Federal standards.</i></p>  | MT have brought some federal labeling standards into state law. It may wish to consider where additional labeling is required and an exemption could be sought.   |
| Warnings about safety                                    | <p><i>This is a matter exclusively within the legislative control of the states.</i></p>  | This is a power which Montana could use but has not to date.  |

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| of food             |   |  |
| Retail food outlets | <i>Yes, but agreement between Federal and State Governments that States may regulate outlets serving food</i>   | Yes, Montana is using this power.  |
| Food transport      | <i>State requirements are preempted if it is not possible to comply with the federal standards when complying with the state standards or the state standards are an obstacle to accomplishing or carrying out the fed standard.</i>  | MT does not seem to have laws on food transport.   |
| Farms               | Yes   | No   |
| Pesticides          | <p><i>- Federal legislation: no state may establish any regulatory limit on a 'qualifying pesticide chemical residue' in or on any food if a 'qualifying federal determination' applies to the presence of such chemical residue on food, unless the state regulatory limit is identical to the federal limit. But State may petition the responsible federal agency for authority to establish a different regulatory limit for a pesticide.</i></p> <p><i>- The preemption regarding the regulatory limits for pesticides does not prevent a state from requiring that food containing a pesticide residue bear or be the subject of a warning relating to the presence of the pesticide.</i></p> | MT has a power to make regulations to prescribe tolerances for pesticide chemicals. Whether or not in accordance with the regulations promulgated under the federal act. It does not seem that this rule-making power has been used. However, use of the rule-making power contrary to the reqs of the federal law would be preempted. |

As highlighted in Table 1, there are a number of areas in which Montana may want to reconsider its approach to regulation to more fully utilize the legislative powers at its disposal. Firstly, there are matters that Montana is not regulating at all, despite these areas being open to regulation by Montana. This is the case with establishments where meat is slaughtered, packed, canned or rendered ('meat processing plants'). At present, Montana does not regulate meat-processing plants. While Montana cannot impose standards that are in addition to, or different from, Federal standards, there is no constitutional barrier to it regulating meat-processing plants. For example, a most significant area in which Montana is completely failing to use its legislative authority is in imposing safety warnings on food. This is a highly important State legislative power, which enables States to require that warnings about the safety of food or components of food be placed on labels or otherwise brought to the attention of the consumer. This area is not limited by any express preemption clause. This will be discussed further in Part 4.

Secondly, Montana is not exercising its legislative authority to the full extent in several areas. It has enacted legislation but it has taken a minimalist approach. Although there is, of course, no obligation on a legislature to fully exploit its legislative capacity, there are areas of food safety that may benefit from further regulation. The particulars of the recommended additional regulation will be discussed in Part 4. At this point, we wish to point out the legislative

powers that are available to Montana to be further utilized. For example, in relation to foods other than meat, eggs and poultry ('other food'), it is open to Montana to impose more exacting standards than those in the Federal regulations. Montana's standards for other food generally reflect the Federal standards which it adopted as they appeared as at 1 April 2001.<sup>1</sup> These standards may, in many instances, be adequate, but where they are found to be lacking, Montana has available to it the legislative authority to impose more exacting standards.

Finally, the Federal statutes provide scope for the States to seek exemptions to Federal standards in relation to some food safety matters. This is the case with pesticides. Montana should consider this option seriously in situations where there is a strong public health case to be made for imposing a different standard to that found in Federal regulations. For example, an application for exemption for the setting of a pesticide tolerance in excess of the Federal standard could be made where there is a strong case.<sup>2</sup>

### **3. MODELS FOR REGULATING FOOD SAFETY**

Taking into account the extent of the Montana legislature's authority to regulate food safety as discussed above, this Part of the Review presents a range of regulatory models that could be employed by Montana. Some of these options are already in use, while others represent 'best practice' aspirations. This Part of the Review also identifies some of the concerns and considerations about food and consumer safety from key organizations, such as the Government Accountability Office and the Association of Food and Drug Officers, which are relevant to the assessment of Montana's laws and recommendations for reform in Part 4 below.

#### **a. Federal laws**

An option for States is to use the Federal food safety statutes and regulations as a model for State laws. The State laws would then match the Federal laws. This approach avoids the problems posed by preemption of State laws that exceed Federal standards. It is efficient and administratively easy in the sense that the State simply 'copies' the Federal standard and limits its independent policy consideration of food safety issues. In many instances, the Federal standards are informed by cutting-edge science, are developed by expert agencies, in consultation with informed stakeholder groups, and clearly represent the best current approach to protecting the public's health and safety. It also means that states have the same standards for regulating food in intrastate commerce that the federal agencies have for products for products in interstate commerce. It avoids the situation where the same product is subject to different standards depending on whether it is in interstate or intrastate commerce.

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<sup>1</sup> MONT. ADMIN. R. 37.100.101. The Federal regulations which are adopted by Montana are specifically listed in this regulation. They are extensive and cover many areas of food regulation, including color additives, infant formula, shell eggs, fish and fishery products, milk and cream, cheeses and related products, cereal flours and related products, fruit pies, and canned vegetables.

<sup>2</sup> 21 USC § 346a(n)(5) (2006).

However, it should also be kept in mind that, in some areas, the States have broader legislative power and could enact laws in areas that go beyond the Federal laws. Simply 'cutting and pasting' the Federal laws limits the potential contribution which State law and regulation can make to ensuring that the food supply is safe for human consumption. The Federal laws are also far from perfect and, whilst some aspects of them may prove to be the best model for Montana, it would not be a step forward to stop at the line set by the Federal laws.

### **i. Association of Food and Drug Officials Uniform State Food, Drug and Cosmetics Bill**

The *Uniform State Food, Drug and Cosmetic Bill* ('AFDO Uniform Bill') was accepted and endorsed by the Executive Association of Food and Drug Officials at a meeting in June 1964 and was last revised in 1984. It is modeled on the Federal *Food, Drugs and Cosmetics Act* ('the Federal Act'), however the Federal Act has been amended many times since the last revision of the Uniform Bill in 1994. States may enact the Uniform Bill into State law and thereby achieve some uniformity of food, cosmetic and drug regulation with Federal law. However, as the Uniform Bill has not been updated for 14 years, it would be best to draft a revised version of Uniform Bill to incorporate the current provisions of the Federal Act.

### **ii. Federal Regulations**

Following the approach of adopting the Uniform Bill or an updated version of it into State law, a State may also consider adopting some of the regulations made under the Federal Act ('Federal Food Regulations'). They put the 'meat on the bones' of the Federal Act and set specific standards for many food safety issues. They are revised regularly and reflect current views standards to be observed in order to limit the risk of food-borne illness in humans.

The Federal Food Regulations are complemented by the *FDA Manufactured Food Regulatory Program Standards* ('Manufactured Food Program Standards') which were issued in May 2007 by the FDA. These Standards establish a uniform foundation and best practice for the design and management of State programs responsible for the regulation of plants that manufacture, process, pack or hold foods in the USA. The Manufactured Food Program Standards address ten key areas. They reflect the standards and processes set in the Federal Regulations.

### **iii. FDA Standards: The Food Code**

The FDA's *Food Code 2005*, updated by the *Food Code Supplement 2007* ('the Food Code'), is a set of model food safety guidelines for food retail operations and institutions. The *Food Code* has been issued in revised forms in 1993, 1995, 1997, 1999, 2001 and 2005. The next version of the *Food Code* will be released in 2009. 48 of the 50 US States and 6 US Territories have reported that they

have adopted at least one edition of the *Food Code*. 29 States or Territories have self-reported adoption of the 2001 or 2005 versions of the *Food Code*.<sup>3</sup>

The *Food Code* provides ‘a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry’. High food safety standards and proper enforcement of such standards in relation to retail and food service establishments are essential. Such sites have been identified by the Centers for Disease Control with five of the major contributing factors to the food-borne illness outbreaks.

The *Food Code* is designed to be consistent with Federal food laws and regulations. Use of the *Food Code* contributes to consistency of national food regulatory policy. It is envisaged that the *Food Code* could be enacted into statute as an act of a State legislative body or promulgated as regulation by a governmental administrative agency with rule-making authority.

Some of the details of the *Food Code* are set out below. The *Food Code*:

- has the purpose of safeguarding public health and providing consumers food that is safe, unadulterated and honestly presented;
- applies to ‘food establishments’, which means an ‘operation that stores, prepares, packages, serves, vends or otherwise provides food for human consumption’ such as a restaurant, satellite or catered feeding location, catering operation providing food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution or food bank’ or ‘an operation that relinquishes possession of food to a consumer directly or indirectly through a delivery service...’;
- includes provisions regarding Management and Personnel and the competency, standards and conduct required of such persons;
- includes highly detailed provisions to meet the condition that food be safe, unadulterated and honestly presented, with special requirements for highly susceptible populations; and
- includes a comprehensive compliance and enforcement regime.

The *Food Code* is complemented by a set of *Draft Voluntary National Retail Food Regulatory Program Standards* (‘Retail Food Program Standards’), which were last updated in December 2007. The Retail Food Program Standards assist with implementation of the *Food Code* by outlining specific procedures which need to be followed in order to further compliance with the *Food Code*.

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<sup>3</sup> US Food and Drug Administration, ‘Real Progress in Food Code Adoptions’, November 2007, found at <http://www.cfsan.fda.gov/~ear/fcadopt.html#adopt> (accessed 24 September 2008).

## **b. Reforms to Federal Laws**

Some of reforms proposed to the Federal laws highlight the direction in which Montana may wish to develop its food safety laws.

### **i. Food Safety Modernization Act**

A current Bill before the US House of Representatives entitled the *Food Safety Modernization Act* envisages a number of changes to the US food safety system. The Bill was introduced on 26 September 2008 by Representative Rosa L. DeLauro and has been referred to the House Committee, the Committee on Energy and Commerce, and the Committee on Agriculture. The Bill is a slightly amended version of the earlier *Safe Food Act*.<sup>4</sup> The changes proposed the Bill which are relevant to Montana include:

- compulsory annual registration of all food manufacturing, processing, holding or transport establishments;
- preventative process controls to reduce adulteration of food and performance standards for contaminants in food;
- frequent inspection of food establishments;
- a crime of 'bribing' a food inspector;
- food safety standards for 'food production facilities' – being a farm, ranch, orchard, vineyard, aquaculture facility or confined animal-feeding operation.
- programs for certification of imported foods;
- a trace back system to retrieve the history, use, and location of an article of food through all stages of its production, processing and distribution;
- accreditation of laboratories;
- mandatory recall powers;
- civil penalties up to \$1 million per violation;
- criminal penalty of up to 1 year in prison or up to 5 years in prison for severe violations;
- whistleblower protection; and
- civil actions by citizens.

### **ii. Government Accountability Office**

In April 2007, the Government Accountability Office ('GAO') designated the Federal oversight of food safety as a 'high-risk area'.<sup>5</sup> The classification is 'intended to raise the priority and visibility of government programs which are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability and sustainability'. Among the GAO's reasons for

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<sup>4</sup> The *Safe Food Act*, HR 1148, 110th Cong., 1st sess., was introduced on 16 February 2007 by Representative Rosa L. DeLauro with 22 Democrat co- sponsors. The Bill is currently before the House Agricultural Committee and the House Sub-Committee on Health (by referral from the House Energy and Commerce Committee).

<sup>5</sup> Government Accountability Office, *Federal Oversight of Food Safety: High Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs* (2007).



the classification were the fragmentation of the Federal oversight of food, the lack of resources available to the FDA which is responsible for about 80% of the food supply (but accounted for only 24% of Federal government expenditure on food, compared to the USDA being responsible for 20% of the food supply but accounting for 80% of Federal expenditure) and the lack of a mandatory and effective food recall power in the Federal agencies. Each of these reasons for the high-risk designation signal that Federal reform is needed, but they also signal areas in which State regulators can respond to fill major gaps in food safety regimes. The fact that the FDA is under-equipped to deal with the 80% of the food supply which falls within its remit suggests a possible focus for State action. The fact that the lack of a recall power in the Federal agencies is a matter of such concern to the GAO would indicate that States should consider implementing such a power.

In September 2008, the GAO issued a report, insisting that improvements are need in the FDA oversight of fresh produce. The FDA has no formal program for regulating fresh produce. It has not issued specific regulations for the prevention of contamination in fresh produce. Fresh produce establishments were irregularly inspected. This is another area in which State intervention could be highly valuable, especially in light of the recent adverse incidents caused by contaminants in fresh produce.<sup>6</sup>

### **c. Other State laws**

Many US States have introduced food safety laws that parallel the Federal laws to a considerable extent. Individual States or local authorities have also enacted laws that take additional steps towards addressing perceived risks posed by food. California has been the most activist State in relation to food safety. A number of the policies pursued by State and local agencies is set out below:

- *Toxic and carcinogenic chemicals:* California's *Safe Drinking Water and Toxic Enforcement Act*, also known as Proposition 65, is one of the most well-known State efforts to protect consumers against toxic substances ('Proposition 65').<sup>7</sup> Proposition 65 applies to 700 chemicals which have been identified as carcinogens or reproductive toxicants. Proposition 54 does not restrict the amount of these chemicals which is permissible in consumer products, but it does require that manufacturers give a clear and reasonable warning notification before knowingly or intentionally exposing a person to a significant risk from one of these chemicals. The standard warning is 'This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.' The failure to give a warning where the amount of the chemical exceeds the allowable or 'safe harbor' level may give rise to liability. An allowable level is not set by the State of California for all listed chemicals, which

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<sup>6</sup> Government Accountability Office, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce* (2008).

<sup>7</sup> CAL. HEALTH & SAFETY CODE § 25249.5 *et seq*

means that the company using the chemical must prove that the chemical has been used to a safe harbor level.

- *Genetically-engineered ('GE') foods*: nearly half of all US States have enacted one or more statewide or local regulations relating to GE foods. There is increasing regulation of genetically engineered products, including bans on such foods or requiring labeling of such foods. Articles in relation to which laws have been passed include rice,<sup>8</sup> fish species,<sup>9</sup> seeds,<sup>10</sup> and pesticides.<sup>11</sup>
- *Organic foods*: some States have adopted Federal laws regarding organic produce. California and Washington require registration of organic food producers.<sup>12</sup>
- *Recalls*: some States have introduced requirements that producers or processors of recalled meat or poultry notify the State regulatory agency of the names and details of all customers who have received or are due to receive the recalled product.<sup>13</sup>
- *Calorie count information*: some State and local authorities have required that chain restaurants put calorie counts on all food items on their menus.<sup>14</sup>
- *Trans fats*: some State and local authorities have banned trans fats in some food products.<sup>15</sup>

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<sup>8</sup> See, eg, CAL. FISH & GAME CODE § 55000-55108 (2000); ARK. CODE ANN. § 2-15-201-20 (2005).

<sup>9</sup> CAL. FISH & GAME CODE § 15007 (2003); ALASKA STAT. § 16.40.210 (1990); 2003 Mich. Pub. Acts No. 270.

<sup>10</sup> IND. CODE § 15-4-13 (2002); ME. REV. STAT. ANN. Tit 7, § 1052 (2001).

<sup>11</sup> MINN. STAT. § 18B.285 (1991).

<sup>12</sup> CAL. HEALTH & SAFETY CODE § § 110810 – 959; Washington State Administrative Code 16-157.

<sup>13</sup> CAL. HEALTH & SAFETY CODE § § 110806-110807. The provision overcomes the problems created by States signing confidentiality agreements with Federal agencies, in particular the USDA, to prevent the States revealing the identifying establishments which may have received recalled products.

<sup>14</sup> CAL. RETAIL FOOD CODE § 114094 (2008); Center for Science in the Public Interest, *California First State in Nation to Pass Menu Labeling Law* (Press Release, 30 September 2008). California is the first State to have taken this step, but it has been taken by local authorities in some parts of the US, including in New York City and Seattle. The New York requirement has been challenged by the New York State Restaurant Association. The case is pending before the US Federal Court of Appeal.

<sup>15</sup> This has occurred in California, New York City, Philadelphia, Stamford, Connecticut, and Montgomery County, Maryland have banned trans fats in food produced in specific establishments such as restaurants and retail establishments producing baked goods: see Centre for Science in the Public Interest, 'California Terminates Artificial Trans Fat', news release, July 25, 2008; Jennifer Steinhauer, 'California Bars Restaurant Use of Trans Fat,' *New York Times*, July 6, 2008.

#### **d. Other Reform Initiatives**

##### **i. Safe Food International/ WHO/ FAO**

In 2005, Safe Food International, an initiative of the Centre for Science in the Public Interest ('CSPI'), a non-governmental organization based in the US, prepared *Guidelines for Consumer Organizations to Promote National Food Safety Systems* ('Safe Food Guidelines'). The Guidelines have been endorsed by the World Health Organization ('WHO') and the Food and Agriculture Organization ('FAO'). Whilst the Guidelines do not take the form of model legislation, they identify all of the elements which Safe Food International consider necessary for an integrated, coordinated and highly effective food safety system.

The CSPI, independently of Safe Food International, and the Consumers Federation of America ('CFA') have, on many occasions, expressed similar views to those in the Safe Food Guidelines. There seems to be considerable unity in their positions on the changes which are needed to improve the US food safety system.

In summary, the Safe Food International Guidelines provide for:

- a food-control management structure which has responsibilities to establish regulatory measures, monitor system performance, facilitate continuous improvement and provide overall guidance and leadership. The management structure needs to include a lead food safety authority. The lead food safety authority must not have conflicting missions of regulation and promotion of the food industry;
- specific and mandatory standards for disease-causing organisms, naturally-occurring contaminants such as aflatoxin, pesticide residues and environmental contaminants such as lead and methyl mercury. In particular, the Guidelines suggest that all substances added to food and all new technologies that change the safety or nutritional quality of food should be shown to be safe before they are permitted on the market. They also maintain that feed for food producing animals, including feed additives and drugs for food-producing animals, should be shown to be safe for both humans and animals. They also hold the view that feed for ruminants which will be served as food to humans should not contain ruminant tissues or by-products;
- labeling requirements for food, including ingredients in descending order by weight, presence of allergens, date marking, instructions for safe use and storage, presence of genetically modified ingredients, identification of origin of foods;<sup>16</sup>

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<sup>16</sup> CFA and CPSI maintain that the growers and processors should be required to mark fruits and vegetables to enable produce to be traced to its source. This is essential when the produce is implicated in an outbreak.

- a strong surveillance system to track information on illnesses, gather information to identify outbreaks (defined as two or more illnesses linked to a single hazard), link outbreaks to food sources, and trace the food identified in the outbreak back to its origins. An effective surveillance system can identify food-borne illness outbreaks whilst there is still time to remove the contaminated food from the market and prevent illnesses, particularly if food has been intentionally contaminated. There should be coordination in the surveillance system between Federal and State agencies;
- an inspection system to ensure that laws and policies are effectively enforced. The inspection should extend from farms to processing plants, transportation and points of sale, including restaurants, street vendors and other retailers. Inspections should be based on risks posed by different foods and the history of problems in a particular sector of the food industry. There needs to be proper selection and training of food inspectors;<sup>17</sup>
- a recall and tracking system to enable the removal of contaminated or mislabeled food from the market. Compliance with a recall order must be mandatory, with penalties for those who refuse to comply;<sup>18</sup>
- food monitoring laboratories which are accredited according to an established certification program for laboratories; and
- information gathering and dissemination systems for consumers and industry, including publishing annual food-borne disease incidence trends, results of routine sampling and analysis of food products, early alerts for outbreaks and food contamination.

The CSPI adds an important component that is missing from the Guidelines: enforcement and compliance. This would include powers to detain and/ or

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They maintain that each operator in the food chain should mark the produce with their details. If there is repacking of food and mixing of food from different sources, the details of source should be maintained on the food despite the repacking: see Michael F. Jacobson, Caroline Smith DeWaal and Chris Waldrop, 'Letter to Dr Andrew C. von Eschenbach, Commissioner', *FDA* (July 3, 2008).

<sup>17</sup> CFA strongly opposes privately-funded inspections by industry-paid auditors. CFA states that 'on site inspection of all food processing facilities by public officials sworn to protect the public interest is essential to assuring the program works well and earns the public's trust': Consumer Federation of America, 'CFA Praises Elements of Senate Food Safety Modernization Act; Challenges Failure to Require Regular Federal Inspection of All Food Processing Plants,' news release, August 1, 2008.

<sup>18</sup> A mandatory recall system is a central tenet of CFA's vision for an improved food safety system in the US: Consumer Federation of America, 'CFA Praises Elements of Senate Food Safety Modernization Act; Challenges Failure to Require Regular Federal Inspection of All Food Processing Plants,' news release, August 1, 2008.

condemn food, prosecute and/ or seek civil remedies from violators of food safety standards, and whistleblower protection.<sup>19</sup>

The Guidelines also lay down the following general, over-arching principles for food safety systems.

- food safety systems need to be focused on preventing problems with food. The food safety system should not be reactive only;
- continuous improvement in food safety should be the aim;
- laws should apply from 'farm to kitchen',<sup>20</sup>
- high standards of health protection should be observed;
- standards and requirements should be based on scientific evidence that is high quality, transparent and independent and, at a minimum, in line with standards, guidelines and other recommendations of the Codex Commission;
- laws should put primary responsibility for producing safe food on producers and processors;
- laws should be monitored and regularly evaluated to ensure that all stakeholders' requirements are being met; and
- laws should apply to food aid during times of food security emergencies.

## **ii. Institute of Medicine**

The Institute of Medicine ('IOM') asserts that an effective food safety system begins with a 'clear, unified mission that focuses and integrates the varied needs and responsibilities of all stakeholders, gives the stakeholders a basis for achieving the goals of the system, and is broadly accepted.'<sup>21</sup> Whilst the IOM's review focused on the Federal food safety system, it emphasized that food safety is the responsibility of diverse stakeholders – government, the private sector and consumers – and that partnerships between these groups are essential to building a cohesive, successful framework for food safety. For government, the IOM insisted that it use a science-based, risk analysis to guide its regulation of food safety, that it engage in adequate monitoring and surveillance, that it have effective and consistent regulation and enforcement, and that it allocate adequate human and financial resources to the task of developing and implementing the food safety system. In the IOM's view, the private sector has the primary responsibility of ensuring food safety. Consumers also have a key role. This means that there should be proper consumer education about food

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<sup>19</sup> Centre for Science in the Public Interest, *Building a Modern Food Safety System: For FDA Regulated Foods* (Washington: 2007) 10 – 11.

<sup>20</sup> The view that regulation of food should begin at the farm level and extend to the kitchen is shared by CFA and CPSI. These organizations express considerable concern that there is an absence of regulation of farms. They maintain that farms should have written food safety plans to identify where contamination is likely to occur and the steps which must be taken to prevent it: see Michael F. Jacobson, Caroline Smith DeWaal and Chris Waldrop, *Letter to Dr Andrew C. von Eschenbach, Commissioner, FDA* (July 3, 2008). CPSI has pointed to the Codex Alimentarius Commission, *Code Of Hygienic Practice For Fresh Fruits And Vegetables*, as a source of standards for fresh fruit and vegetable production.

<sup>21</sup> Institute of Medicine, *Ensuring Safe Food: From Production To Consumption* (Washington: National Academies Press, 1998).

safety and consumers should be given opportunities to participate in the development of food safety standards.

### **iii. Association of Food and Drug Officials**

The Association of Food and Drug Officials ('AFDO') has recently outlined some of the reforms which it considers important to the development of improved food safety operations in the US.<sup>22</sup> It emphasizes the integral role played by State and local agencies in these operations and the expertise and capacity of those agencies to respond quickly to food safety concerns. In order to enhance the functioning of State and local agencies, AFDO make a number of recommendations that are relevant to this Review of Montana's food safety laws. AFDO highlights that States should be recognized and remunerated for the major role they play in food safety. AFDO recommend as follows:

- Federal food safety agencies should be authorized to share food product distribution information with State and local governments during the course of outbreak investigations, recalls and other food emergencies. At present, food product distribution information is held as proprietary information by Federal agencies, who cannot share this information with State agencies without imposing significant restrictions on the use of the information. These restrictions undermine the potential benefit of the information to State and local agency efforts to bring in suspect foods;
- There should be more cooperative programs between Federal agencies and the States for food safety. These programs reduce duplication of effort and create some national uniformity of standards;
- Federal agencies should establish protocols by which they accept State inspection and food sampling analytic work. The FDA does not accept State inspection and analytical data;
- States should have an expanded role in inspecting imported foods; and
- States should be properly funded by the Federal government to undertake food safety activities. State and local safety inspectors perform more than 80% of all food safety inspections in the US. FDA contracts for a small number of inspections, whilst State and local agencies fund most of the inspections.

## **4. REVIEW OF MONTANA'S FOOD SAFETY LAWS**

This Part of the Review presents our views and recommendations regarding Montana's food safety laws. We use the Framework and Principles on Food and Consumer Safety, in combination with the detail of our preferred regulatory model: the Safe Food Guidelines. We endorse the Safe Food Guidelines, because they are a comprehensive, public health-oriented, forward-looking set of food safety principles. There is also considerable agreement among food safety agencies and experts with the concepts embodied in the Guidelines. In the

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<sup>22</sup> Association of Food and Drug Officials, 'AFDO Position Statement Regarding: New Federal Food Safety Legislation', news release, August 4, 2008.

analysis below, we have supplemented the Guidelines with the best aspects of the other regulatory models outlined in Part 3.

#### **e. Montana's Food Safety Laws**

MT's Food Safety Laws are principally found in the following statutes and administrative rules:

- *Food, Drug and Cosmetic Act* ('*FDCA*'): <sup>23</sup> the *FDCA* is based on the AFDO Uniform Bill and contains very few additional provisions. Montana has made only one rule under the power granted in the *FDCA* ('*FDC Rule*'). <sup>24</sup> In this rule, Montana adopted into State law over 60 Federal food, drug and cosmetic regulations. The Federal regulations deal with detailed matters, such as color additives, food additives, food labeling, infant formula, eggs, fish, milk and cream, cheeses, frozen desserts, canned fruits, frozen vegetables and an array of other food matters;
- *Retail Food Establishments* ('*Retail Food Establishments Statute*'): <sup>25</sup> Montana has made detailed rules under the power granted in this statute in relation to food service establishments ('*Food Service Establishments Rule*') <sup>26</sup>, food manufacturing establishments ('*Food Manufacturing Establishments Rule*') <sup>27</sup>, and vending of food and beverages. <sup>28</sup> The *Food Service Establishment Rules* and, to a lesser extent, the *Food Manufacturing Establishments Rules*, are based on the *Food Code* 1999. Montana has not adopted an updated version of the *Food Code*.
- *Wholesale Food Establishments* ('*Wholesale Food Establishments Statute*'): <sup>29</sup> Montana has made no rules under the power granted in this statute; and

There are some additional rules in relation to food safety in other Montana statutes and administrative rules, such as those in relation to bed and breakfast establishments, schools etc. These are not the focus of the analysis here.

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<sup>23</sup> MONT. CODE ANN. TITLE 50, CHAPTER 31.

<sup>24</sup> MONT. ADMIN. R 37.110.1.

<sup>25</sup> MONT. CODE ANN. TITLE 50, CHAPTER 50.

<sup>26</sup> MONT. ADMIN. R 37.110.2.

<sup>27</sup> MONT. ADMIN. R 37.110.3.

<sup>28</sup> MONT. ADMIN. R 37.110.4.

<sup>29</sup> MONT. CODE ANN. TITLE 50, CHAPTER 57.

**f. Analysis of Montana's Food Safety Laws**

**i. Food safety mission, functions and infrastructure**

MT's Food Safety Laws are almost silent on the mission, functions and infrastructure of the State's food safety agencies. The *Retail Food Establishments Statute* and the *Wholesale Food Establishments Statute* set out a basic purpose for the statute: 'to prevent and eliminate conditions and practices that endanger public health'.<sup>30</sup> The MT Food Safety Laws refer to the Department of Public Health and Human Services ('Department'), local boards of health, local health officers and local sanitarians as agencies involved in food safety ('Health Agencies').<sup>31</sup> The MT Food Safety Laws set out some specific duties and the powers of the Health Agencies.<sup>32</sup>

We consider the absence of provisions that clearly define fundamental aspects of Montana's food safety infrastructure and management is a significant omission. We acknowledge that any changes to the MT Food Safety Laws would occur in the context of the 'Montana Public Health Statute Modernization Project' ('Public Health Statute Modernization') and those reforms provide a clear purpose for the Montana public health system, the general powers and duties of the Department, and the expectation and powers for the Department to establish strong collaborative relationships with Federal, local, tribal and other State public health agencies, and other public sector agencies.<sup>33</sup>

However, even with the Public Health Statute Modernization, we consider that MT's food safety regime could be improved by clearly stating the purpose of the food safety system, identifying the agencies which have responsibility for food safety, and identifying the agencies' general duties, responsibilities and powers. We consider it important that there be an overarching statement of purpose for the food safety system in Montana that is included in a food safety statute. A statement of purpose brings focus to the work of the agencies. A food safety statute should also identify which agency is the 'lead food safety agency' and the exact authority and responsibility of each agency for food safety in the State. As it seems from MT's Food Safety Laws that the local authorities play an important role in the system, it is particularly valuable for a food safety statute to delineate the agencies' distinct spheres of duty and power. A general duty statement for each agency in the system provides an objective basis for assessment of the agencies' performance. A mission and duty statement can also make clear that food regulatory agencies must not pursue competing commitments to promote the interest of the local food industries, but must make the safety of consumers the key priority.

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<sup>30</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-101; *Wholesale Foods Establishments Statute*, MONT. CODE ANN. § 50-57-101.

<sup>31</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-102(17) (definition of 'regulatory authority'); *Wholesale Foods Establishment Statute*, MONT. CODE ANN. § 50-57-101(8) (definition of 'regulatory authority').

<sup>32</sup> For example, *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-301(1) ('State and local health officers and others shall make investigations and inspections of establishments once per year'); *FDCA*, MONT. CODE ANN. § 50-31-104 (Department authorized to adopt Federal regulations).

<sup>33</sup> Public Health Statute Modernization Act, H.B. 92, 60th Leg. (Mont. 2007).



Like with the Public Health Statute Modernization, we would recommend that there be a detailed section in a food safety statute regarding collaboration and relationships between public and private sector partners. This is not developed in MT's Food Safety Laws. Integrated and responsive relationships with Federal and local authorities are essential to the success of food safety programs in the US, with each level of government having an indispensable role to play in the system. With the challenges faced by the FDA in exercising effective oversight of the foods within its portfolio of responsibilities, there are many opportunities for the States to collaborate with the Federal agencies to protect the United States' food supply. A section focusing on relationships with other governmental agencies may provide the impetus for Montana to consider entering more partnership and contracts with Federal agencies to carry out key food safety functions under State law and under Federal law as agents of the Federal government. Our research suggests that Montana has some agreements or State contracts with the FDA regarding food safety. Many other States have more agreements with the FDA and, as the AFDO notes, the States have extensive capacity to carry out functions in a more expeditious and effective manner than is possible for Federal agencies. The statute should also encourage collaborations with the private sector. As the IOM argues, the private sector – as food producers and retailers – have the primary responsibility for maintaining the safety of the food we consume. The statute must therefore enable Montana's food agencies to work closely with private entities to facilitate their fulfillment of their responsibilities.

Food safety is a science. Credentialing and training of personnel from State agencies with responsibility for designing and implementing food safety standards is essential to the integrity and quality of the food safety system. There is very little in MT's Food Safety Laws at present about credentialing and training of personnel. The only provision relates to inspectors of *retail* food establishments; the credentialing and training of other food safety personnel, including inspectors of *wholesale* food establishments, is not mentioned. In the *Retail Food Establishments Statute*, there is a requirement that a person completing an inspection of an 'establishment' must be 'certified and have completed a food safety training program, such as the program administered by the national restaurant association educational foundation or its equivalent.'<sup>34</sup> Proper licensing and on-going training of food inspectors is vital to ensuring that there is strict compliance with food safety standards and procedures. As regards certification and training, we would recommend that Montana adopt the standards for credentialing and training of regulatory personnel, in particular inspectors, in the FDA's *Manufactured Food Program Standards* and *Retail Food Program Standards*. These Standards define the essential elements of a training program for regulatory staff. It does not seem that Montana uses these Standards at present.

There is nothing in MT's Food Safety Laws that sets continuous improvement of the food safety system as a concrete goal and guiding principle

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<sup>34</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-301(2).

for Montana. There is nothing in MT's Food Safety Laws that mandates regular and systematic review of those laws with a view to making revisions which will enhance the effectiveness of the food safety system. It is recommended that Montana have a statute that provides a goal and a mechanism for continuous development and improvement of the Montana food safety system.

In one instance, MT's Food Safety Laws refers to a 'food safety task force or advisory council', which could assist with developing administrative rules under the *Retail Food Establishments Statute*.<sup>35</sup> There are no provisions empowering the establishment of the advisory council or setting out its role and purpose in the Montana food safety system. It would be valuable for a food safety advisory council to be enshrined in the Montana food safety system through legislation.

## ii. *Standards for safe food*

A food safety system must include specific, current, science-based, public health-oriented standards and controls to prevent the 'adulteration' of food through disease-causing organisms, naturally-occurring contaminants, pesticide residues, food additives, or environmental contaminants. These controls must be aimed at prevention of food-borne illness, either by preventing adulteration of the food or preventing the adulterated food being consumed. MT's Food Safety Laws provide a reasonable set of preventative controls for safe food. There is scope for considerable improvements to these controls in relation to:

- Clarifying which food establishments are subject to food safety laws
- Licensing of establishments in the food chain
- Using Federal standards for food safety
- Setting standards for retail food establishments
- Setting standards for wholesale food establishments
- Setting standards for 'farms'
- Emerging food issues

*Food establishments which are subject to food safety laws:* The Montana Food Safety Laws do not cover the range of entities which are part of the food chain. They do not cover farms (or 'food production facilities' as they are called in the *Federal Food Safety Modernization Act*). Putting farms aside for the present (and they will be specifically examined below) and starting from the point at which food leaves the farm, Montana's regulation of the other entities in the food chain is patchy. The problem seems to arise, in part, from a lack of consistency and clarity in Montana's use and definition of key terms relating to the different entities and stages in the food supply. This means that it is uncertain which MT's Food Safety Laws apply to which types of food establishments. It also means that some food establishments fall outside the reach of regulations that should apply to them. For example, the *Wholesale Food Establishments Statute* and the *Retail Food Establishments Statute* are intended to apply to establishments at

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<sup>35</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-103.

different stages of the food supply. There are no rules made under the *Wholesale Food Establishments Statute*, which means that there are basically no standards or preventative controls that apply to 'wholesale food establishments' in Montana. This is a major gap. However, under the *Retail Food Establishments Statute*, Montana has made *Food Manufacturing Establishment Rules* which apply to 'food processing establishments'<sup>36</sup> and which seem to be intended and, in fact, are applied to 'wholesale food establishments'.<sup>37</sup> It is questionable whether there is authority under the *Retail Food Establishments Statute* to make rules that apply to 'wholesale manufacturing establishments'. This problem seems to arise from a lack of clarity about the naming and definition of the different entities that Montana wishes to regulate for the purposes of food safety. There are other examples of this same problem in MT's Food Safety Laws. We recommend that there be identification of all the entities that should be regulated for food safety in Montana and terminology developed to refer to those entities which is consistently used across all statutes and administrative rules.

*Licensing:* MT's Food Safety Laws envisage the regulation of 'retail food establishments' and 'wholesale food establishments'.<sup>38</sup> There are a number of deficiencies with the licensing regime which need to be remedied. Firstly, there are detailed rules for the licensing of 'food service establishments'<sup>39</sup> but there are no rules at all for the licensing of types of 'retail food establishments' other than 'food service establishments' or for licensing 'wholesale food establishments'. There is technically an absence of legal regulation applicable to licenses for a significant number of food establishments in Montana. Secondly, there needs to be clarification of the subjects of the Montana's Food Safety Laws (as discussed above) to ensure that the licensing requirement covers all food establishments and that there are no gaps in the licensing scheme.

In relation to licenses, there are improvements that could be made to the license application and issuance process as it appears in MT's Food Safety Laws. There are some basic details in the *Retail Food Establishments Statute*, *Wholesale Food Establishments Statute* and *Food Service Establishments Rules* about the application process for licenses. In this regard, we recommend adopting the approach in the *Food Code*, which elaborates very detailed rules for the contents of license applications, the qualifications and responsibilities of applicants for licenses, the responsibilities of the regulatory authority at the time a license is issued, the responsibilities of the license holder.<sup>40</sup> We consider it particularly important to set out the responsibilities of applicants for licenses and license holders. On this point, we would recommend that Montana remove the provision that the issuance of a license is a right 'unless grounds exist for denial

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<sup>36</sup> *Food Manufacturing Establishments Rule*, MONT. ADMIN. R. 37.110.301(11).

<sup>37</sup> The Montana Department of Public Health and Human Services website lists the *Food Manufacturing Establishments Rules* as applicable to wholesale food establishments.

<sup>38</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. §§ 50-50-201 – 217; *Wholesale Food Establishments Statute*, MONT. CODE ANN. §§ 50-57-201 – 211.

<sup>39</sup> *Food Service Establishment Rules* 37.110.238 (##what is the symbol for a rule?)

<sup>40</sup> *Food Code* ¶¶8-302-11 – 8.304.20.

or cancellation'.<sup>41</sup> Whilst it may be desirable to limit the discretion of the licensing agency to refuse a license and to set objective criteria for the issuance of a license, it is unnecessary to state that the issuance of a license is a 'right'. It does not fit with the public health orientation of the licensing scheme to create a right in an individual applicant for a license. For similar reasons, we disagree with the current approach that a license may not be denied by the Department without giving reasons to the applicant and a chance to respond.<sup>42</sup> We prefer and suggest the approach in the *Food Code* where there is a requirement that reasons for a refusal of a license be given and that the applicant be given the opportunity to appeal the decision.<sup>43</sup> This is a more efficient system in which the onus is on the applicant to appeal and not on the Department to provide a hearing *before* making its decision about whether to grant a license.

Where a license has been granted, we cannot identify a power in MT's Food Safety Laws to summarily suspend (as opposed to cancel) a license on appropriate grounds. The *Food Code* provides for summary suspension of licenses where there is an 'imminent health hazard' and sets down the procedures which must be followed for suspending the license and removing the suspension.<sup>44</sup> Presently, Montana can only 'remove' a license by cancelling the license which requires a prior hearing.<sup>45</sup> It is proper that a license may only be cancelled by way of a determination following the opportunity for a fair hearing. However, it is important for the protection of the public that there be a power to suspend the license of an establishment which poses an urgent risk to the public's health.

*Using Federal standards for food safety.* In setting standards for food safety, Montana has used the Federal standards in many instances, including in the *FDCA*, the *FDC Rule*, the *Food Service Establishments Rule*, and the *Food Manufacturing Establishments Rule*. Where Montana is preempted from regulating differently than or in addition to the Federal legislature, we recommend that Montana enact the most recent Federal standards for food safety into State law. Enacting these standards enables Montana to regulate in the same areas, to the full extent permitted by the Federal legislature. However, at present, Montana is not relying on the most current versions of Federal laws. For example, Montana is using the *Food Code* 1999 that was significantly changed in the 2005 version and its 2007 supplement. The changes to the *Food Code* have been made to reflect revelations about the sources and risks of food-borne illness and improved scientific understanding about ways to combat such risks.<sup>46</sup>

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<sup>41</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-204.

<sup>42</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-211.

<sup>43</sup> *Food Code* ¶¶8-303-30.

<sup>44</sup> *Food Code* ¶¶8-804-10 – 8.804.50.

<sup>45</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-211; *Food Service Establishment Rules*, MONT. ADMIN. R. 37.110.238(5) – (11).

<sup>46</sup> US Food and Drug Administration, 'Summary of Changes: 2001 FDA Food Code' (2001); US Food and Drug Administration, '2005 Food Code: Summary of Changes' (2005).

Where Federal law does not preempt Montana law, there is scope for Montana to explore a range of innovative regulatory controls to bring security to the food supply. Some of these are outlined further below.

*Controls for retail food establishments:* To regulate retail food establishments, Montana has detailed rules – setting specific and mandatory standards and preventative controls – for ‘food service establishments’ and ‘food manufacturing establishments’, but it does not have rules for all types of ‘retail food establishments’. The controls which exist are detailed and cover matters such as food storage and protection, materials for equipment and utensils, utensil design and fabrication, sewage, plumbing, toilets and hand washing etc.<sup>47</sup> However, the rules – which are such an essential part of the food safety system because the statutes are almost silent on the issue of specific standards – must be applicable to all food establishments within the regulatory authority of Montana. No food establishment should be left out. Again, clarifying the subject of the food safety regulations will assist in addressing this concern.

Montana is using an outdated version of the *Food Code* to regulate retail food establishments. The failure to use the updated *Food Code* means that Montana’s food safety standards do not reflect the most up-to-date food science. There are potentially serious consequences of failing to use current preventative controls. Some of the most far-reaching changes in the *Food Code* since 1999 have been in relation to the health of ‘food employees’, the responsibilities of the ‘person in charge’ of a food establishment for removing, restricting and reporting food employees who pose a risk of food-borne disease transmission and the capacity of the regulatory authority to restrict or exclude food employees.<sup>48</sup> These particular provisions are absent from the Montana statute and rules, which only provide that a ‘diseased person shall not handle food’.<sup>49</sup> We would recommend that Montana incorporate the *Food Code* 2005 and its 2007 Supplement into its laws. Given the timing of Montana’s consideration of these issues, it may be that the 2009 version of the *Food Code* will be available.

*Controls for wholesale food establishments:* As has been noted above, Montana uses rules it has made for ‘food manufacturing establishments’ to regulate ‘wholesale food establishments’. The *Wholesale Food Establishments Statute* is also applicable to wholesale food establishments, but, as noted above, it has no rules – and therefore no detailed standards – made under it. At present, the rules for food manufacturing establishments seem to be drawn from the *Food Code* 1999 and, to some extent, from the Federal regulations. They are reasonably detailed standards in MT’s Food Safety Laws but they need to remain in step with the prevailing food science. For this reason, MT should consider updating its laws for wholesale food establishments to match the Federal regulations for

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<sup>47</sup> *Food Service Establishments Rules*, MONT. ADMIN. R. 37.110.204 – 242; *Food Manufacturing Establishments Rules*, MONT. ADMIN. R. 37.110.301 – 370.

<sup>48</sup> *Food Code* ¶¶2-201-11 – 2.201.13.

<sup>49</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-105; *Wholesale Food Establishments Statute*, MONT. CODE ANN. § 50-57-105.

manufactured foods and the *Food Code 2007*. The FDA's *Manufactured Foods Regulatory Standards* also provide relevant benchmarks for regulating wholesale food establishments.

*Controls for farms:* There is very little regulation of food safety on farms at either the Federal or State level. Montana currently has no legislation addressing standards or preventative controls for farms. At the Federal level, the Federal Safety Inspection Service of the USDA has no authority to regulate farms and the FDA has limited oversight of animal feed and drug therapies. Many other countries have implemented 'farm to fork' food safety networks in order to monitor on-farm practices in order to improve animal and plant health. Unfortunately, adulteration of food is occurring too frequently at the farm stage and is not being identified at later stages of food processing. Food that is adulterated at the farm stage can contaminate other non-adulterated food it comes into contact with during processing. We would recommend for Montana to give consideration, like in the *Food Safety Modernization Act* before Congress, to regulating food safety on farms.<sup>50</sup>

*Emerging food issues:* There are various food safety concerns which are not currently in MT's Food Safety Laws but which the Federal agencies, other States and/ or local agencies have been active in regulating. These include organic foods, genetically engineered foods, and trans fats in food. We would recommend that Montana give consideration to whether it wishes to address any of these issues in its food safety legislation. This is arguably a step on from making food 'safe' to making food 'healthy'.

#### *g. Labeling requirements*

The area of food labeling is one particularly affected by the preemption provisions. In relation to all food products, the States are preempted from imposing different or additional requirements to the Federal labeling standards. We recommend that Montana continue to ensure that its labeling standards match all of the Federal standards for food.

There is also scope for Montana to take greater steps in relation to food labeling than it currently takes. As discussed above, the States are empowered to impose requirements for warnings about the safety of food or ingredients in the food. This does not seem to be a power which Montana has introduced into MT's Food Safety Laws. It is highly valuable power and has been seized by States, such as California, to enable the conveyance of a wide range of information about food to consumers. The requirement that chain food store include calorie count information is imposed by way of an exercise of this power. We suggest that it is a power that Montana may want to give to the Department in a new statute.

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<sup>50</sup> *Food Safety Modernization Act*, HR7143, 110<sup>th</sup> Cong., 2d sess, sec. 206.

Montana may also want to consider introduce a labeling system for food that allows for the tracing of foods back to each grower and processor in the food supply who ‘handled’ the food. Where there is an outbreak of food-borne illness, having a trace back system allows for faster identification of the source of the contaminated food, recall of those products from the market and prevention of illness in others. It would significantly improve the ability of the Department to respond in a highly effective manner to food-borne illness. The proposed trace back scheme in the *Food Safety Modernization Act* provides a worthwhile model for Montana. It envisages a traceability system that allows the regulator to retrieve ‘the history, use and location of an article of food through all the stages of its production, processing and distribution’.<sup>51</sup>

#### *h. Surveillance system*

It is important that Montana have a vigilant surveillance system to track information on food-related illnesses and trace contaminated food to its source. MT’s Food Safety Laws do not address the question of surveillance. Montana may wish to consider the introduction of laws that clarify the power of the Department to obtain and collect information relevant to food safety and the duties of individuals or agencies to report risks to the safety food supply. The *Turning Point Model Public Health Act*, although not specific to food safety, could provide a model for such laws.<sup>52</sup>

#### *i. Inspections*

The inspection of food establishments for compliance with regulatory controls is fundamental to an effective food safety system. Inspection is very important for identifying establishments that are not meeting standards, reinforcing the requisite standards, and removing adulterated food from the food supply. In Montana, provision is made in the Food Safety Laws for inspection of retail food establishments and wholesale food establishments.<sup>53</sup>

As discussed above, having properly trained inspectors are essential to the operation of inspection programs. We also note the importance of ensuring the independence, impartiality and integrity of inspectors and the protection of the inspection program from interference. We understand that inspectors who live in the same community in which they are conducting inspections can particularly experience pressure to see that establishments pass their inspection. The *Food Service Establishment Rules* make the interference with the Department or an authorized person in the performance of their duties a ground

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<sup>51</sup> *Food Safety Modernization Act*, HR7143, 110<sup>th</sup> Cong., 2d sess, sec. 210(1).

<sup>52</sup> *Turning Point, Model Public Health Act* sec 5-102 – 5-103.

<sup>53</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-301 – 305; *Wholesale Food Establishments Statute*, MONT. CODE ANN. § 50-57-301 – 304. There are detailed rules for inspections in relation to food service establishments: *Food Service Establishments Rules*, MONT. ADMIN. R. 37.110.239. The rules relating to food manufacturing establishments expressly adopt the rules for inspection of food service establishment: *Food Manufacturing Establishments Rules*, MONT. ADMIN. R. 37.11.371. There are no rules for inspections of wholesale food establishments, but, as has been noted on several occasions, it seems that the rules on food manufacturing establishments are applied to wholesale food establishments.

for cancellation of an establishment's license.<sup>54</sup> We agree that this should be a potential ground for cancellation of a person's license. However, we would also suggest that this should be an offence under the statute for which a penalty may be imposed. This conduct should be punished where it occurs, with a view to signaling the seriousness of acts that seek to undermine the inspection program and to deterring others from engaging in such behavior.

The *Retail Food Establishments Statute* envisages that inspections of 'retail food establishments' will take place annually.<sup>55</sup> This schedule is modified in the rules to twice every 12 months, on the understanding that inspections must take place as 'often as necessary' to enforce the rules.<sup>56</sup> There are no provisions setting out any criteria to be used for determining the frequency of inspections. We refer to the *Food Code* and suggest that Montana could consider a similar provision outlining the performance history and industry risk factors that must be used to determine inspection schedules.<sup>57</sup> We would also suggest that the inspections at least follow the requirements for inspection content and procedures to be found in the *Food Code*, the *Manufactured Food Program Standards* and the *Retail Food Program Standards*. Where there are violations of the food safety standards identified during an inspection, the *Food Code* sets tighter time frames for correcting violations. We consider that the more onerous standards in the *Food Code* should be adopted.<sup>58</sup>

MT's Food Safety Laws require that inspectors have free access to establishments at any reasonable time.<sup>59</sup> There is no provision within MT's Food Safety Laws to address the situation where an inspector is refused access. This is a gap which should be closed. We would suggest that this can be done by introducing a provision like in the *Food Code* to enable an order to be made by the regulatory authority for access to the establishment<sup>60</sup> and for a record to be made in the inspection report of the refusal of access.<sup>61</sup> If the order of the regulatory authority is not complied with, the *Food Code* empowers the regulatory authority to seek an order from a court.<sup>62</sup>

MT's Food Safety Laws do not make clear the powers which inspectors have where food is found to be adulterated or misbranded. On the one hand, the *Retail Food Establishments Statute* provides that an officer may make a report recommending that food be withheld from sale.<sup>63</sup> The provision does not indicate to whom the report is made and what happens when a recommendation is made. The provision also only empowers the making of a recommendation that the food be withheld from 'sale' and does not cover other situations in which an

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<sup>54</sup> *Food Service Establishment Rules*, MONT. ADMIN. R. 37.11.238(5).

<sup>55</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-301.

<sup>56</sup> *Food Service Establishments Rules*, MONT. ADMIN. R. 37.110.239(1).

<sup>57</sup> *Food Code* ¶8-401.20.

<sup>58</sup> *Food Code* ¶¶8-405.11, 8-405.20, 8-406.11.

<sup>59</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-302; *Food Service Establishment Rules*, MONT. ADMIN. R. 37.11.239(2).

<sup>60</sup> *Food Code* ¶8-401.40.

<sup>61</sup> *Food Code* ¶8-401.30.

<sup>62</sup> *Food Code* ¶8-809.10.

<sup>63</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-304.



establishment may be providing food to people other than by way of a seller/buyer relationship. This provision should be removed from the statute. The *Food Service Establishments Rules* empower the Department to detain and tag food which is adulterated or misbranded, to seek an order for the destruction of such food or to destroy food which is contaminated or filthy.<sup>64</sup> We suggest that there should be improvements made to this enforcement process in line with the *Food Code*, which provides detailed procedures for the holding, examination and destruction of food.<sup>65</sup>

*j. Compliance, enforcement and due process*

A regulator of food safety should have available to it a clearly-stated set of powers for achieving compliance with food safety laws. These powers should be exercised in accordance with due process requirements which should also be spelt out in the statute or rules. There are improvements which could be made to MT's Food Safety Laws in relation to compliance and enforcement. We have already recommended above the inclusion of powers and procedures for issuance of licenses, summary suspension of licenses, cancellation of licenses, inspection of premises, and holding, tagging and destruction of food. We recommend that there be changes in relation to:

- the system for criminal or civil liability for violations of food safety laws;
- the power of the Department to recall unsafe food;
- protection for whistleblowers; and
- the procedure for administrative or judicial review of decisions made under MT's Food Safety Laws.

At present, MT's Food Safety Laws envisage that there can be misdemeanor prosecutions of individuals for purposeful or knowing violations of the Food Safety Laws<sup>66</sup> and civil penalties imposed on establishments that violate the laws.<sup>67</sup> The *FDCA* provides that before a prosecution for a violation proceeds, the person to be prosecuted shall be given the opportunity to present his views before the Department about the potential proceedings.<sup>68</sup> Whilst this type of 'discussion' may occur as an informal part of the prosecutorial process, we do not think it appropriate to enshrine this step in a public health statute. It formally focuses the system on the position of the food establishment and the operators of those establishments in a way which is not defensible in terms of the aims of the statute or the requirements for due process. We would also recommend a review of the penalty system in Montana for food safety violations.

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<sup>64</sup> *Food Service Establishments Rule*, MONT. ADMIN. R. 37.110.240.

<sup>65</sup> *Food Code* §§8-803.10 – 8-803.90.

<sup>66</sup> *FDCA*, MONT. CODE ANN. § 50-31-506; *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-108; *Wholesale Food Establishments Statute*, MONT. CODE ANN. § 50-57-108

<sup>67</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-109; *Wholesale Food Establishments Statute*, MONT. CODE ANN. § 50-57-109.

<sup>68</sup> *FDCA*, MONT. CODE ANN. § 50-31-504.

The penalties are very low (\$50 – \$200) compared with those being contemplated in the Federal *Food Safety Modernization Act*.<sup>69</sup>

There is a power for the Department to seek an injunction against any continued violation of the laws.<sup>70</sup> This is a very useful power to retain in the statute. This enables the Department to seek take steps to stop the conduct which is undermining or has the potential to undermine the safety of food. However, an injunction will not enable adulterated or misbranded food to be recalled. There is no power in the Department to make a voluntary or mandatory ‘recall order’. It is essential that the Department be empowered to exercise control over the adulterated food, require the responsible establishment to cease distribution of the food, notify (and require the responsible establishment to notify) all persons further down the food supply chain that to cease the handling of such food, notify consumers who received the food, notify the public about the retail establishments where the food was distributed from the food supply which is adulterated or misbranded. It is inadequate for a Department to only be able to recommend to a food establishment that it recall food which it produced or sold which is unsafe. There may be consequences for an establishment which refuses to recall products in terms of tortuous liability and reputational damage, but it is a weak regulatory system in which the government agency with responsibility for the food safety system cannot take steps to remove food from the market which is unsafe. A model for a recall power is to be found in the Federal *Food Safety Modernization Act*.<sup>71</sup> We recommend that this be considered as a good option for Montana.

An interesting provision that Montana may want to consider and which is also in the Food Modernization Act is a protection for whistleblowers, which includes employees of food establishments, who provide information regarding violations of food safety laws or threats to the public health.<sup>72</sup>

At present, MT’s Food Safety Laws do not clearly set out the path and procedures to be followed by the Department when it wishes to enforce its powers. A statute should make clear the power of the Department to make certain decisions (eg, to issue a permit) or to take certain action (eg, to order access to a food establishment where it is being denied by the license holder). A statute should also make clear when the Department must apply for an order from an administrative body or a court to take certain action (eg, cancellation of a license, prosecution of an establishment for a violation of the laws). The statute should also make clear the procedures that must be followed by the Department, an administrative body or a court making a decision under a food safety statute (eg, the form of a notice of an application for a hearing for an order to cancel a license, the length of the notice period etc). The statute should also make clear the authority of an administrative body or a court to make an order in relation to

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<sup>69</sup> *Food Safety Modernization Act*, HR7143, 110<sup>th</sup> Cong., 2d sess, sec. 405.

<sup>70</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-106; *Wholesale Food Establishments Statute*, MONT. CODE ANN. § 50-57-106.

<sup>71</sup> *Food Safety Modernization Act*, HR7143, 110<sup>th</sup> Cong., 2d sess, sec. 403.

<sup>72</sup> *Food Safety Modernization Act*, HR7143, 110<sup>th</sup> Cong., 2d sess, sec. 407.

food safety. On the other side of the coin, a statute should set out the right of an individual or a legal entity to seek review of, or appeal, a decision of the Department or to stay a decision of the Department (eg, a decision to summarily suspend a license, a decision to destroy food). The procedures that must be followed for the individual to seek a remedy from an administrative body or a court should be clearly outlined in the statute. MT's Food Safety Laws do not address most of these questions. A revision of the laws should consider clarifying the substantive and procedural aspects of enforcement of food safety regulations. Some guidance can be obtained in this respect from the *Food Code* 2005, Appendix A. However, we also consider that there could be improvements to this model to make it clearer and easier to use.

*k. Structure of MT's Food Safety Laws*

Moving away from the substance of MT's Food Safety Laws, we wish to draw to your attention to some of the structural improvements that could be made to MT's Food Safety Laws. It is often the case that provisions dealing with very different subject matter are put together in the same part of a statute. On the other hand, provisions that could be grouped together are found in different parts of the statute. For example, we would strongly suggest that a new statute have a section on 'Compliance and Enforcement' in which all such provisions are to be found. This of course facilitates the reading and comprehension of the statute. We would also note that some matters would be better included in the rules, rather than in the statute. Power should be given for the making of rules to deal with such matters. For example, there are specific provisions on labeling of honey and hamburgers in the *FDCA*, whilst details regarding standards for all other foods are in the rules.<sup>73</sup> Thirdly, we have observed that many headings in the statute do not match the content of the related provision. This is seen, for example, in the rule headed 'Submission of plan of correction as bar to cancellation'.<sup>74</sup> This provision is about a bar to *prosecution* for a violation and is not about *cancellation* of a license. These are all minor points but worth tidying up in any legislative review.

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<sup>73</sup> *FDCA*, MONT. CODE ANN. § 50-31-204 (honey); § 50-31-204 (hamburger mix).

<sup>74</sup> *Retail Food Establishments Statute*, MONT. CODE ANN. § 50-50-210.